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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,665	07/13/2001	Giancarlo Santus	6485/16895US2	3102

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EXAMINER	
OSTRUP, CLINTON T	

ART UNIT	PAPER NUMBER
1614	6

DATE MAILED: 03/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/903,665	SANTUS ET AL.	
	Examiner	Art Unit	
	Clinton Ostrup	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-25 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 08/383,707 .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claims 1-25 are pending in this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 13-16 depend from a method of claim 8, however, claim 8 is drawn to a dosage form. Therefore, claims 13-16 are vague and unclear. For purposes of examination the examiner assumed claims 13-16 depend from the independent method claim 12, however, correction by applicant is required to clear up the ambiguous claim dependencies of these claims.

Claims 19, 20, and 25 contain the trademark/trade name KETOROLAC™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade

name is used to identify/describe KETOROLAC™ and, accordingly, the identification/description is indefinite.

Regarding claims 19, 20, and 25, the phrase " ketorolac-based " renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Any remaining claims are rejected as depending on indefinite base claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-51 of U.S. Patent No. 6,333,044. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both claim the same compound, used in similar compositions and using similar methods of treatments of said compound.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-
(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 1, 2, 5, 6, 8-9 rejected under 35 U.S.C. 102(b) as being anticipated by Muchowski et al., **4,089,969.**

Muchowski teaches 5-aroyl-1, 2,dihydro-3H-pyrrolo [1,2-a] pyrrole-1-carboxylic acid compounds for administration in any appropriate pharmaceutical composition via any of the accepted modes of administration of agents for the treatment of inflammation, pain, or pyrexia, or the prophylaxis thereof. The reference teaches how the compositions will include conventional pharmaceutical carriers or excipients and may be in the form of solids, liquids, suppositories, solutions, suspensions, emulsions, creams, lotions, ointments and the like. The amount of active ingredient is taught by the reference to be between 25 to 500 mg daily, thus meeting the specific amount limitations of instant claim 2. The reference describes how suppositories will include polymers such as polyalkylene glycols and aqueous dextrose to form a solution of suspension. See: col. 1, lines 5-40; col. 9, line 19 – col. 10, line 15; col. 11, line 27 – col. 12, line 23; and abstract.

Although the reference does not specifically describe the composition as being in an intranasally administrable form, this is an intended use of a composition and is not given patentable weight in composition claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muchowski et al., **4,089,969** as applied to claims 1, 2, 5, 6, 8-9 and further in view of HISAMITSU PHARMACEUT CO INC, JP 03-072433 (HIMAMITSU) based on the abstract provided and Cetenko et al., **4,943,587**.

Muchowski teaches 5-aroyl-1,2,dihydro-3H-pyrrolo[1,2-a]pyrrole-1-carboxylic acid compounds for administration in any appropriate pharmaceutical composition via any of the accepted modes of administration of agents for the treatment of inflammation, pain, or pyrexia, or the prophylaxis thereof. The reference teaches how the compositions will include conventional pharmaceutical carriers or excipients and may be in the form of solids, liquids, suppositories, solutions, suspensions, emulsions, creams,

lotions, ointments and the like. However, the primary reference lacks the method of nasally administering the composition and the nasal spray of instant claims 12-25.

The amount of active ingredient is taught by the HIMAMITSU discloses a foam aerosol containing non-steroid anti-inflammatory analgesics and a propellant. The primary reference teaches that the composition is useful for the treatment of muscle pain exhibits an excellent drug activity, produces a fine foam when sprayed and does not have any irritation against the mucous membrane of the nose cavity. The reference teaches the foam aerosol as comprising 0.2-5 wt.% of the non-steroid analgesic, 1-20 wt.% of absorption accelerators (e.g. crotamiton, benzyl alcohol, pepper oil, diisopropyladipate, diethylcevasate, or oleyl alcohol), 0.3-10 wt.% of surfactants (e.g. sorbitan fatty acid ester, glycerin fatty acid ester, polyoxyethylene alkyl ether, or/and polyoxyethylene phenyl ether), 0.01-5 wt.% of pH controller (e.g. potassium hydroxide, sodium hydroxide, diethanol amine or triethanol amine), 10-50 wt.% of refined water, and 10-50 wt.% of a propellant (e.g. n-pentane, isopentane, F resin 11, F resin 12, or dimethyl ether). See: abstract.

Cetenko et al., teach a method of delivering hydroxaic derivatives of selected non-steroid anti-inflammatory drugs such as ketorolac, and teach how the formulations are used in association with pharmaceutically acceptable carriers. The secondary reference teaches that the compositions are useful for both veterinary and human medical use and they may be administered nasally. Cetenko et al., teach that formulations suitable for administration to the nose or buccal cavity include powder, self-propelling and spray formulations such as aerosols and atomizers. The secondary

reference teaches that the formulations, when dispersed, should preferably have a particle size in the range of 0.1 to 200 mu. See: col. 1, lines 9-32; col. 8, line 55 – col. 9, line 2; col. 20, line17- col. 23, line 57 and abstract.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the method of administering 5-aroyl-1, 2, dihydro-3H-pyrrolo [1,2-a] pyrrole-1-carboxylic acid compounds for the treatment of inflammation and pain by using the aerosolized formulation as taught by HIMAMITSU and Cetenko et al., because of the expectation of obtaining a foamy aerosolized composition with an excellent drug activity, does not irritate the mucous membrane of the nose cavity, and capable of delivering NSAIDS for the treatment of allergies, psoriasis, inflammation, arthritis, and pain.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Clinton Ostrup
Examiner
Art Unit 1614

March 21, 2002

FREDERICK KRASS
PRIMARY EXAMINER
GROUP 1600